## REMARKS

Claims 38 and 42, which were indicated as defining allowable subject matter, have been amended to independent form and are considered allowable. Their scope remains unchanged.

Claim 34 has been amended to further support the meaning of "therapeutic material" and to distinguish it from "angiogenic substances". Each of claims 34-37 and 39-41 is considered to define patentable subject matter for the reasons discussed below.

**Gambale '126 Does Not Anticipate Any of Claims 34-37 and 39-41.**

Reconsideration is requested of the rejection of claims 34-37 and 39-41 as anticipated under 35 U.S.C. §102(e) by Gambale patent 6,432,126. "To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference arranged as in the claim." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375 (Fed. Cir. 2001). Gambale does not disclose applicant's claimed invention and, particularly, the limitation of thrombus loaded with a therapeutic material whereby the thrombus provides a host matrix for the therapeutic material.

Claim Interpretation – "Therapeutic Material"

"[T]he question of anticipation turns on claim interpretation, a question of law." *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1256, 9 USPQ2d 1962 (Fed. Cir. 1989). The rejection appears to be based on a misinterpretation of the claimed "therapeutic material" and a misunderstanding of the relationship between the claimed thrombus, the therapeutic material and the configuration of the angiogenic implant. In particular, the rejection is based on the notion that "...this angiogenic substance is the therapeutic material" (p. 3 of the action). That is incorrect and ignores the distinctions between "angiogenic substance" and "therapeutic material" as those terms are used in the application. The terms "angiogenic substance" and "therapeutic material" do not mean the same thing, as should be apparent from the context in which those terms are used. Claims must be read "...not only in the context of the particular claim in which [a] term appears, but in the context of the entire patent, including the

specification. *Phillips v. AWH Corp.* (415 F.3d 1303, 75 USPQ2d 1321, Fed. Cir.2005) (en banc). While claims may be given their broadest reasonable interpretation, it is not reasonable to interpret a claim term in a manner that conflicts with the written description. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983). ("Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." (710 F.2d at 802, 218 USPQ at 29 quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976) (emphasis in original)). See, also, MPEP §2111.01.

The invention, as is apparent from its title, relates to "devices and methods for treating tissue" such as muscle tissue that has become damaged, suffers from reduced function or has become dysfunctional. (specification at 5:6-7). The treatment involves application of therapeutic material. The therapeutic material may be pharmacological (1:20-21) or biological (2:19-20). Whether pharmacological, biological or in some other form, the therapeutic material is selected to provide therapeutic benefit to the tissue site. (33: 18-20). In other words, the "therapeutic material" serves to effect treatment of the tissue. For example, reference to "therapeutic material" is repeated throughout the written description and is defined as including:

- tissue cells (4:14-15)
- stem cells (4:15-23)
- cell components such as DNA and proteins (4:15-23)
- pharmacological agents (1:20-26)
- myoblasts (4:15-23)
- cardiomyocytes (4:15-23)
- precursor cells (4:15-23)
- genetically engineered cells (4:15-23)
- growth factors (4:15-23)
- genes (4:15-23)

- DNA (4:15-23)
- inhibitors such a tumor necrosis factors (4:15-23)

Also clear from the context of the written description is that "angiogenic substances" and "therapeutic material" are different and have a different meaning. Indeed, the difference also is explicitly stated in the application, at (7:17-19):

> "Also, the devices may have associated with them **substances that promote angiogenesis**, such as growth factors **separate from the therapeutic material** intended to treat the muscle dysfunction."
>
> (emphasis supplied)

The promotion of angiogenesis serves a separate function and involves characteristics other than those referred to as involving "therapeutic material". The angiogenic function causes new and recruited blood vessels to grow to the area of the implant site so that those blood vessels can supply the therapeutic materials with nutrients. (5:25-6:3). The angiogenic aspect of the invention involves an angiogenic implant configured to mechanically trigger an injury response that leads to angiogenesis. The implant also may include an "angiogenic substance" such as a polymer to create an adverse biological effect. (6:23-7:8). Part of the angiogenic process involves a "coagulation cascade" that includes the development of fibrin and thrombus which "...may hasten revascularization in the subject tissue by providing a ready-made completed fibrin network into which growth factors and endothelial cells may be attracted." (8:10-13). There is nothing in applicant's specification to suggest that an angiogenic substance (e.g., thrombus, fibrin, polymer or other substance adapted to stimulate angiogenesis) is a "therapeutic material" as that term is used in the application. Throughout the application a distinction is drawn between those elements that are employed to stimulate angiogenesis and those that serve to provide a therapeutic function to the tissue. To the extent the rejection is based on the notion that the "...angiogenic substance is the therapeutic material", that conclusion necessarily ignores the entire context of the application and the use of those terms and is in error.

Claim 34 recites several elements in combination including the scaffold, thrombus and a therapeutic material. In the context of the present specification, the thrombus serves to enhance the angiogenic function as well as to provide a host matrix for the separate and distinct therapeutic material. They are not the same.

Properly interpreted, claim 34 is not anticipated by Gambale. Although Gambale does disclose an implant associated with thrombus, it does not disclose or suggest the claimed limitation of the thrombus being loaded with a therapeutic material so as to provide a host matrix for the therapeutic material.

Each of claims 35, 36, 37 and 39-41 depends directly from claim 34 and is not anticipated by Gambale '126 for the same reasons. Additionally, as to claim 37, there is no disclosure or suggestion in Gambale '126 of the therapeutic material comprising "...at least one of cells, tissue, precursor cells, stem cells, cardiomyocytes, skeletal myoblasts and growth factors."

The application is considered to be in condition for allowance.

Respectfully submitted,

Arthur Z. Bookstein
Reg. No. 22,958
Attorney for Applicant
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111
Tel: 617-261-3100
Fax: 617-261-3175

Date: March 20, 2006